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Title: Issues Management Process Course # 38401

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# Issues Management Process Course #38401

Ula Marie Binion, Issues Management SME Quality and Performance Assurance – Performance Assurance

2017



# Housekeeping

- Introductions
- Fire Exits
- Restroom Locations
- Breaks





### **Ground Rules**

- Have Fun
- Respect Others
- Be Present
- Participate
- Ask Questions
- Share Ideas and Examples
- Listen to Others
- Limit Side Conversations
- Respect Time





# **Purpose**

The purpose of this training it to advise Issues Management Coordinators (IMCs) on the revised Contractor Assurance System (CAS) Issues Management (IM) process.





# **Objectives**

### Terminal Objectives

- Understand the Laboratory's IM process
- Understand your role in the Laboratory's IM process

### Learning Objectives

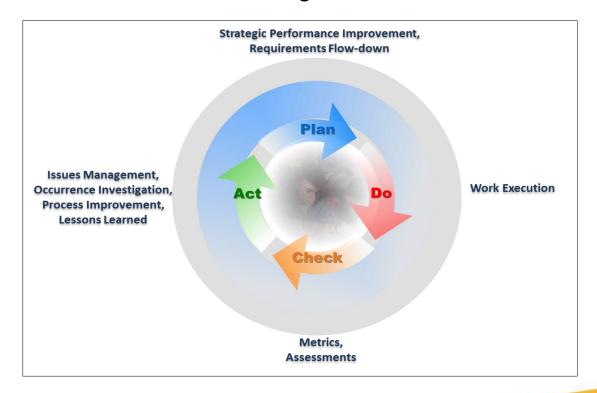
- Describe the IM process within the context of the CAS
- Describe the importance of implementing an institutional IM process at LANL
- Describe the process flow for the Laboratory's IM process
- Apply the definition of an issue
- Use available resources to determine initial screening risk levels for issues
- Describe the required major process steps for each risk level
- Describe the personnel responsibilities for IM process implementation
- Access available resources to support IM process implementation





# **Contractor Assurance System**

CAS is a performance-based system that provides evidence to assure work is being performed safely and in compliance with all requirements, and risks are identified and managed.







# **Contractor Assurance System**

Per DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*, and Clauses H-3 and H-4 of the Prime Contract, LANL is required to have a CAS system in place to ensure effective, safe, and secure work. As part of its CAS program, DOE O 226.1B requires the Laboratory to have an IM process that allows for the effective identification, categorization, evaluation, and correction of issues.

SD320, Los Alamos National Laboratory Contractor Assurance System, is the system description document for the LANL CAS program.

CAS is a performance-based system that provides evidence to assure work is being performed safely and in compliance with all requirements, and risks are identified and managed. It builds on quantifiable data, supports line management, and facilitates executive decision making and continuous improvement. CAS enables LANL to track performance, characterize and manage risk based upon analysis and data, improve management and performance, and facilitate the accessibility of data for oversight purposes.

CAS is comprised of a Plan, Do, Check, Act framework that recognizes LANL as a complex system of institutional processes that may be measured individually and as a whole. Each component of the Plan, Do, Check, Act framework enables CAS to support and monitor safe, secure, and efficient mission delivery.





# **Contractor Assurance System**

The Plan, Do, Check, Act components consist of processes and associated tools that work together to create a mature CAS program:

- Strategic Performance Improvement aligns organizational and individual work to ensure Laboratory Mission, Vision, Values, and Goals are met
- Requirements Flow-down ensures work is authorized and executed in conformance with the Prime Contract via clearly defined contractual requirements which serve as the basis for policies and procedures
- Metrics help managers evaluate performance against goals, targets, and benchmarks to create an environment for aligned and fact-based improvement of LANL performance
- Assessments provide a mechanism for the Laboratory to systematically observe processes and operations and evaluate performance or compliance gaps
- Issues Management ensures issues are identified, categorized by risk, communicated, and corrected in a timely manner, and that implemented corrections are effective/sustainable
- Occurrence Investigation and Reporting ensures DOE and NNSA are informed about adverse events and promotes organizational learning to support continuous improvement
- Process Improvements implements process improvements across LANL using a suite of process improvement approaches (e.g., LSS methodology, Kaizen methods, etc.)
- Lessons Learned captures and shares learning from operating experience to avoid similar events, anticipate and mitigate undesirable consequences, and replicate best practices





# **Issues Management**

The IM process ensures issues are identified, categorized by risk, communicated, and corrected in a timely manner, and that implemented corrections are effective and sustainable.

"An issue ignored is crisis ensured."

(Regester and Larkin, 2008)

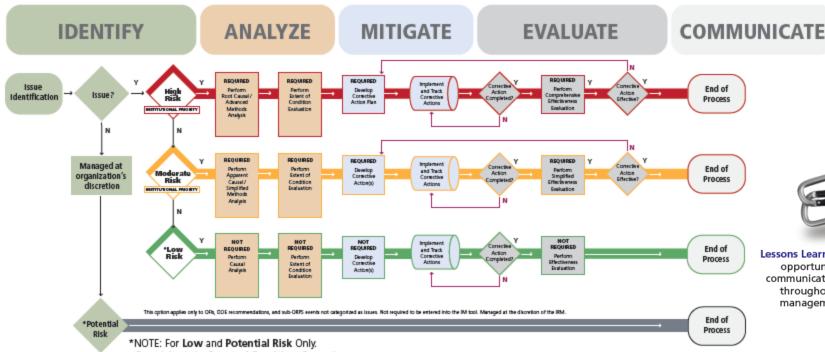






# **Issues Management Process**

An issue is a failure to meet a documented requirement that results in a risk to performance





Lessons Learned and learning opportunities may be communicated at any point throughout the issues management process.

\*NOTE: For **Low** and **Potential Risk** Only.

Causal Analysis, Extent of Condition, Corrective
Actions and Effectiveness Evaluations are managed
at the discretion of the IRM.





# **IM Process Components**

**IDENTIFY** 

ANALYZE

**MITIGATE** 

**EVALUATE** 

COMMUNICATE

- Identify Identify issue and determine risk level based on screening criteria.
- Analyze Analyze the issue to understand the cause and extent of the issue.
- Mitigate Develop corrective actions to address and resolve the identified issue.
- Evaluate Evaluate the issue to determine if corrective actions taken to address the identified issue were effective and sustainable.
- Communicate Communicate identified issues, resolution, and effectiveness to appropriate audiences.



# **IM Process Requirements by Risk**

INSTITUTIONAL PRIORITY	High Risk (Institutional Priority)	Moderate Risk (Institutional Priority)	Low Risk	Potential Risk
Risk Criteria	Includes but is not limited to the following:  • Significant negative impact or significant deficiencies related to mission or operations  • Significant compliance issues related to health, safety, security, environment, or waste  • Significant negative impact on cost, scope, schedule of key project deliverables  • Systemic ineffective resolution of issues  • Compensatory measures not sufficient to mitigate risk  • Institutional effort is required to mitigate risk	Includes but is not limited to the following:  Negative impact or deficiencies related to operations or mission  Risk to cost, scope or schedule of key projects / deliverables  Compliance issue related to safety, environment, waste, security*	Includes but is not limited to the following:  • Minimal negative impact to operations or mission	Potential risks identified from opportunities for improvement (OFIs), DOE recommendations, and Sub-ORPS (that are not categorized as issues) may be documented in this category.  Although not required to be entered into the IM tool they may be precursors to larger issues that warrant further review.  OFIs, DOE recommendations, and Sub-ORPS are managed at the discretion of the IRM.





	High Risk (Institutional Priority)	Moderate Risk (Institutional Priority)	Low Risk	Potential Risk
Causal Analysis	Root Causal / Advanced Methods	Apparent Causal / Simplified Methods	Not Required	
Compensatory Measures	As Needed	As Needed	As Needed	
Extent of Condition Evaluation	Required	Required	Not Required	
Corrective Actions	Corrective Action plan	Corrective Actions	Corrective Actions as deemed appropriate by IRM	
Effectiveness Evaluation	Comprehensive Approach	Simplified Approach	Not Required	
	IMRB:	MRB:	IRM:	
	Screening	Screening	Screening	
IMRB / MRB (Final approval required)	Root / Advanced     Methods Causal Analysis	Apparent / Simplified Methods Causal Analysis	Causal Analysis (if conducted)	
	Extent of Condition     Evaluation	Extent of Condition     Evaluation	<ul> <li>Extent of Condition Evaluation (if conducted)</li> </ul>	
	Corrective Action Plan	Corrective Actions	Corrective Actions	
	Action / Issue Closure	Action / Issue Closure	Action / Issue Closure	
	Effectiveness Evaluation     Plan and Report	Effectiveness Evaluation     Plan and Report	<ul> <li>Effectiveness Evaluation Plan and Report (if conducted)</li> </ul>	

<sup>\*</sup>Although Table 1 outlines the criteria for each risk level, the IRM/MRB has the latitude, and is ultimately responsible for applying professional judgment when categorizing issues. Once categorized, issues must follow the appropriate risk level requirements. See Section 3.2.3 *Process Requirements by Risk* for more detail.





### **Proposed ORPS Crosswalk to IM Risk Levels**

Table 2. ORPS Crosswalk to IM Risk Levels							
	P322-4 Risk Level						
P322-3 ORPS Report Level	High	Moderate	Low	Potential			
High	Required *						
Low	Optional		Required **				
Informational	IRM Discretion or MRB/IMRB Determination						
Sub-ORPS							

- \* **ORPS Report Level High** events may be categorized as High or Moderate Risk in the IM process, however, recommendations to screen as a Moderate Risk must be approved and documented by the organization's Associate Directorate level MRB.
- \*\* Minimum required.
- ORPS Report Level Low events are categorized, at a minimum, as Low Risk but may be categorized higher, at the discretion of the IRM, MRB, or IMRB.
- ORPS Report Level Informational events may be categorized as High Risk, Moderate Risk, Low Risk, or Potential Risk, at the discretion of the IRM, MRB, or IMRB
- Sub-ORPS events may be categorized as High Risk, Moderate Risk, Low Risk, or Potential Risk, at the discretion of the IRM, MRB, or IMRB



# Risk Issue Examples

#### **High Risk:**

- Radiological release from a transuranic (TRU) waste drum in the underground repository at the Waste Isolation Pilot Plant (WIPP)
- Electrical arc-flash and blast resulting in burns and injuries to employees
- Unauthorized discharge of a weapon during training exercise

#### **Moderate Risk:**

- Inadequate lockout / tag out removal
- Recurring findings regarding the LANL Earned Value Management System (EVMS) and subsequent loss of EVMS certification and credibility

#### Low Risk:

- Inadequate signage in construction area
- Employees delinquent in required training

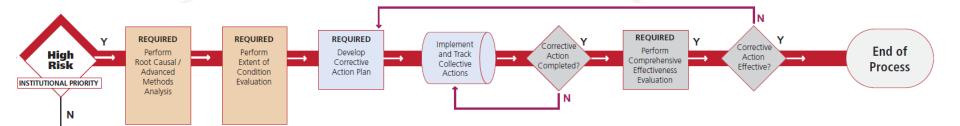
#### Potential risk (OFIs, DOE recommendations, Sub-ORPS):

- Responsibilities not clearly defined in policy/procedure
- Opportunity to improve winter budgeting in all organizations for safety





# High Risk

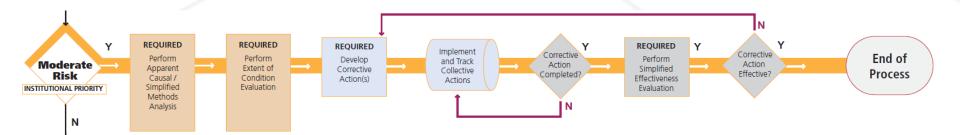


- Causal = Root Causal/Advanced Methods
- Extent of Condition = Required
- Corrective Actions = Corrective Action Plan (CAP)
- Effectiveness Evaluation (EE) = Comprehensive Approach
- Approvals = local organizational MRB then elevated to IMRB
- IM Tool Entry = Required





### **Moderate Risk**

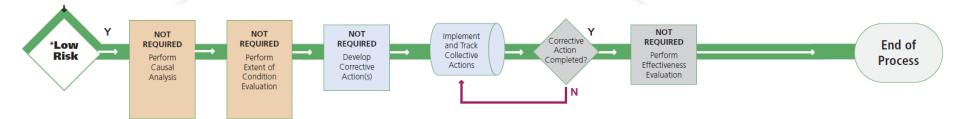


- Causal = Apparent Causal/Simplified Methods
- Extent of Condition = Required
- Corrective Actions = Required
- Effectiveness Evaluation (EE) = Simplified Approach
- Approvals = MRB
- IM Tool Entry = Required
- Alternate Disposition = Pending Resolution





### **Low Risk**



- Causal = Not Required
- Extent of Condition = Not Required
- Corrective Actions = At IRM Discretion
- Effectiveness Evaluation (EE) = Not Required
- Approvals = IRM
- IM Tool entry = Required
- Alternate Disposition = Pending Resolution, Found & Fixed
- \* Can be leading indicators





### **Potential Risk**

\*Potential Risk This option applies only to OFIs, DOE recommendations, and sub-ORPS events not categorized as issues. Not required to be entered into the IM tool. Managed at the discretion of the IRM.

End of Process

Includes: OFIs, DOE recommendations, Sub-ORPS

- Causal = Not Required
- Extent of Condition = Not Required
- Corrective Actions = Not Required
- Effectiveness Evaluation (EE) = Not Required
- IM Tool Entry = Not Required

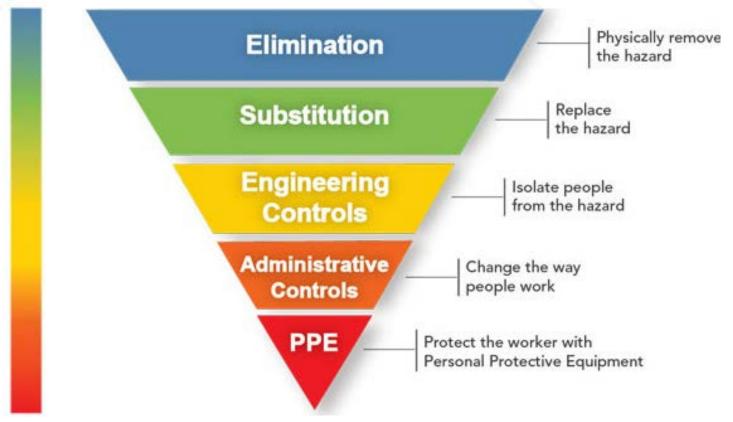




<sup>\*</sup> Can be leading indicators

# **Hierarchy of Controls**

\*Most Effective: Making the Work Safe



**Least Effective: Making the Person Safe** 





### **SMARTER Corrective Actions**

#### Specific

- Directly addresses causes and contributing factors
- Includes who, what, where, when how, how much how long, etc.

#### Measurable

- Progress can be measured
- Completion criteria are defined

#### Accountable

- Responsible party is identified
- Has buy in with all impacted

#### Reasonable

- Doing it because it's needed not because it's easy
- Returns system to normal operations or system performance is enhanced or improved

#### Timely

- Can be completed as soon as practical
- Due dates are defined and obtainable

#### Effective

- Effectiveness evaluation plan or strategy is pre-identified
- Effectiveness evaluation plan or strategy is executed and documented

#### Resilient / Sustainable

- Remain in place over time until / unless they are intentionally discontinued
- Immune to mission, system, org, or personnel changes





# **Objective Evidence**

- It is the responsibility of the IRM to ensure that corrective actions are closed with appropriate, factual OE.
- The IM tool can accept a variety of files or documents as attachments. (Word, Excel, Powerpoint)
- IMCs should ensure that the attached OE, to the best extent possible, is in Adobe PDF form to ensure date integrity and ease of retrieval.
- Objective Evidence that is determined to be Official Use Only (OUO) may be uploaded into the IM tool as long as it is properly labeled; however if the author of the OUO OE determines it has a limited distribution, it should not be uploaded into the IM Tool.





### Items Entered In IM

- The following items should be entered in the IM Tool for appropriate corrective action and resolution
  - Items or conditions that meet the definition of an issue
  - Any identified environmental issues
  - Items or conditions related to LLW/MLLW
  - PAAA/WSH NTS reportable events or conditions
  - ORPS reportable events
  - Items categorized as Sub-ORPS at the discretion of the FOD
  - Any item or condition deemed as an issue as determined by the IRM/MRB





# Items <u>not</u> entered into IM Tool

- The following items <u>must not</u> be entered into the IM Tool
  - Classified, Sensitive, or Unclassified Controlled Nuclear Information (UCNI)
  - Human Resource-related personnel and/or conflict-ofinterest matters
  - Personally Identifiable Information (PII)





### **Price Anderson Act**

- In 1957, Congress enacted the Price Anderson Act to the Atomic Energy Act to provide a mechanism for the public to seek relief in case of a nuclear reactor incident
- Provides compensation and limits contractor liability
- The Act has been extended several times since 1957
  - Current liability limit 13.6 billion per incident



Three Mile Island - 1979





### **Price-Anderson Amendments Act**

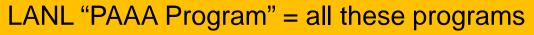
- In 1988, the Price Anderson Amendments Act (PAAA) was enacted to continue this indemnification
- As part of its approach, Congress required DOE-indemnified contractors to be subject to <u>civil penalties</u> for <u>violations</u> of DOE's nuclear safety program
- Over the years, Congress has added more programs
  - 10 CFR 708 DOE Contractor Employee Protection Program (1992)
  - 10 CFR 820 Procedural Rules for Nuclear Safety (1993)
  - 10 CFR 835 Occupational Radiation Protection (1993)
  - 10 CFR 830 Nuclear Safety Management (1994)
  - 10 CFR 850 Beryllium Disease Prevent Program (1999)
  - 10 CFR 851 Worker Safety and Health Program (2006)
  - 10 CFR 824 Classified Information Security (2005)

-PAAA/Nuclear Safety

Worker Safety and Health (WSH)

Classified Information Security (CIS)





### Office of Enforcement

- DOE established the Office of Enforcement (OE) to enforce these regulatory programs
- The overall DOE program objective is one we all share:
  - Self-identify and correct conditions/issues before there is an adverse impact on nuclear safety, worker safety health, and classified information security

LANL PAAA Program is the sole interface with OE



# What is a Noncompliance?

- Noncompliance: A self-identified condition that does not meet a DOE regulatory requirement
  - Reporting a noncompliance does not automatically initiate enforcement action
  - DOE OE evaluates available information to determine whether the noncompliance is significant enough to warrant DOE OE investigation and enforcement action
- Violation: A DOE OE determination, based on investigation, that a contractor failed to comply with an applicable regulatory requirement





# **DOE Expectations of Contractors**

- Contractors should have internal compliance programs ensuring detection, reporting and prompt correction of problems that may constitute, or lead to, violations
  - Before the noncompliances lead to a string of similar and potentially more significant events or consequences
  - Before, rather than after, DOE identifies such violations

DOE has stated that self-identification is "possibly the single most important factor" in considering a reduction in a civil penalty





### **DOE Does Take Enforcement Actions**

- OE Investigations / Fact Findings
  - On-site
  - Extensive
- Outcomes:
  - Notice of Violation
  - Settlement
  - Enforcement Letters
  - No Action
- Have resulted in significant civil penalties

LANL PAAA Program works with Legal Counsel and Senior Management to lead the Laboratory's response





# **Reporting Noncompliances**

- NTS Noncompliance Tracking System
  - DOE system for reporting <u>PAAA /WSH</u> noncompliances
  - LANL PAAA Program describes the event/issue, the noncompliance & the related corrective actions
- SSIMS Safeguards and Security Information Management System
  - DOE classified system for <u>CIS</u> noncompliances and events
  - LANL security SMEs describe the event / issue, the noncompliance & the related corrective actions

Other systems do not count as reporting to OE:

Occurrence Reporting and Processing System (ORPS)

OE closely monitors the system

**Issues Management Tool** 

OE does not have access





#### **LANL P141**

## - PAAA, WSH, CIS Compliance Procedure

- PAAA/WSH/CIS program implementing procedure
  - Defines:
    - Roles and responsibilities for noncompliance identification and reporting processes
    - Expectations for identifying noncompliances and reporting
  - Establishes:
    - Noncompliance Screening
    - Reporting of noncompliances and related corrective actions
    - Tracking and closure of noncompliance reports
    - Responding to OE inquiries and enforcement actions

No DOE Order for PAAA just guidance from DOE OE in Handbook and Overview documents



# **Reporting in NTS**

NTS – DOE OE has established two Basic Ways to be Reportable:

- #1. Event Based
- #2. Programmatic / Repetitive / Other

Improvement Management Coordinators (IMCs) are focused on the Issues Management tool – and support NTS Reporting



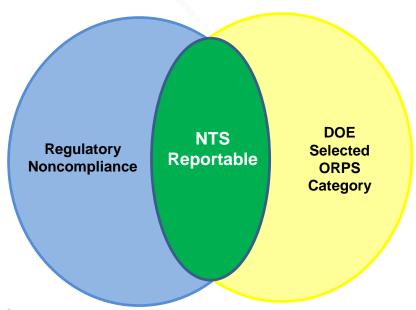


# Two Ways to Become Reportable in NTS #1 - Event Based

#### NTS Reportable Noncompliance

- Regulatory Noncompliance
  - Safety Basis
  - Rad Protection,
  - WSH or
  - Quality

**AND** 



DOE Selected Occurrence Reporting and Processing System (ORPS) Category

Need Both for an Event to be NTS Reportable





# Two Ways to Become Reportable in NTS #2 - Programmatic / Repetitive / Other

#### **Programmatic Deficiencies Involving Noncompliances**

- Weakness in administrative or management controls (or implementation)
- Broad management or process control problem exists
- Requires broad corrective actions

#### **Repetitive Noncompliances**

- Two or more similar noncompliances (from different events / conditions)
- Similar causes / circumstances determined by the causal analysis
- Corrective action not implemented / not effective in preventing recurrence

#### Intentional Violation or Misrepresentation

Also requires a noncompliance

#### **Substantiated Management Reprisals**

Against workers for raising safety issues involving certain regulations

Call the PAAA Program





#### Issues Management ——— PAAA Screening

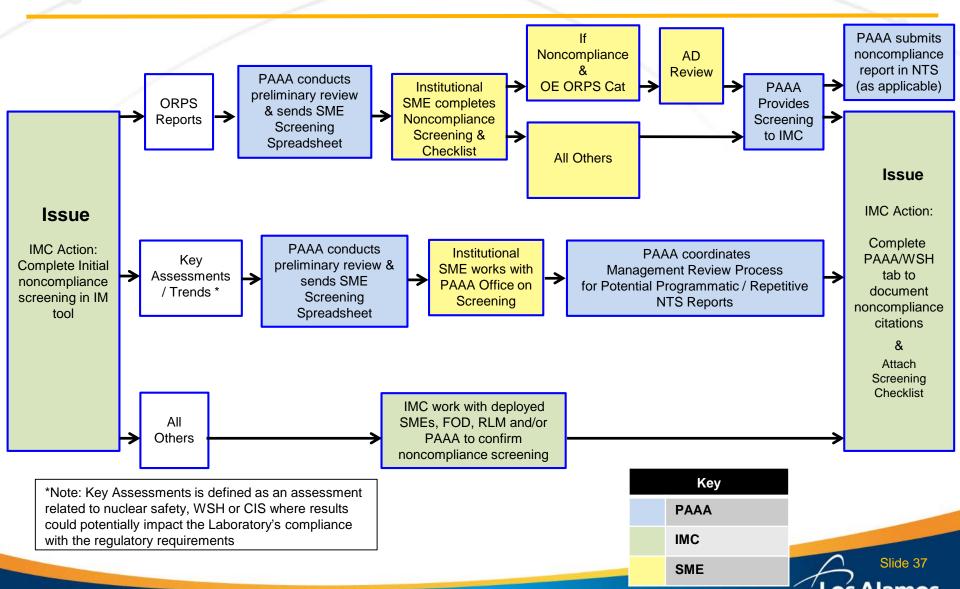
#### **Examples of what is in the IM tool:**

- Events ORPS / Non-ORPS
- Assessments
- Nonconformance Report (NCR)
- Worker awareness and reporting
- Management Observation Verification (MOV)
- Abnormal event process
- Worker Safety Security Teams (WSST)
- PFITS tracking and trending
- Injury/Illness tracking and trending





### **Issue Screening and Reporting Process**





#### It's NTS Reportable – Now What?

- When the PAAA Program enters a report into NTS, the corrective actions generally come from the ORPS report
- It is important to have the right set of corrective actions up front, with each action and deliverable clear and specific
- The Issues Management tool is the system of record for NTS corrective action objective evidence
  - Objective evidence is not uploaded into NTS
  - Hard copy NTS binder is maintained that includes objective evidence

It is important to have the <u>right set</u> of corrective actions up front, with each action and deliverable <u>clear and specific</u>.





#### It's NTS Reportable – Corrective Actions

- We can ONLY close corrective actions in NTS if:
  - Objective evidence attached in PFITS demonstrates that action was effectively completed
  - Evidence must match what was called for in the action.
    - If action lists specific deliverables we need all of them
  - Action(s) is closed in PFITS, per 322-4 requirements
    - Include Management Review Board (MRB)
       review/approval in objective evidence if necessary

Communicate with the PAAA Program when NTSreportable corrective actions are complete, or when due dates are extended.





#### It's NTS Reportable - Closure

- Closure in NTS requires review and sign-off by:
  - PAAA Program Office
  - LANL FOD and Institutional SMEs
  - The Los Alamos Field Office(s)
  - DOE Office of Enforcement
- They review for:
  - The complete picture of the corrective action set
  - The effectiveness of the corrective actions
  - The objective evidence matching what the action called for
  - The adequacy of objective evidence
  - Actions that require additional actions/tracking

Good, Complete Objective Evidence is CRITICAL



## Case Study: TA-54 TSR Violation

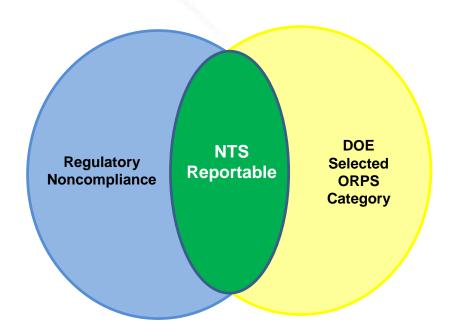
- Two workers performing preventative maintenance were found past the barrier in a 50-foor exclusion area without the proper authorization. In accordance with the Evaluation of the Safety of the Situation (ESS) and implemented via Standing Order (SO) written authorization is required to enter the 50-foot exclusion area. The SO had been assigned as required reading for all workers with access to Area G, which training records indicate that the workers had not completed.
- The event was ORPS reportable under:
  - Group 3A(2), Violation of a DSA hazard control
- This was the only occurrence of workers crossing the barrier
- Local corrective actions were implemented to address the causes of the issue





#### Reference

- Is the IM tool entry associated with an ORPS Report?
- Is the event/issue related to a PAAA or WSH regulatory area?
  - Quality Assurance (10 CFR 830 Subpart A)
  - Safety Basis (10 CFR 830 Subpart B)
  - Radiation Protection (10 CFR 835)
  - Worker Health and Safety (10 CFR 851)
  - Beryllium (10 CFR 850)
- How do you determine if there are noncompliances?
- Identify and explain the noncompliance(s).
- Is the event NTS-reportable?



Need Both for an Event to be NTS Reportable





## Case Study: TA-54 TSR Violation

Is the IM tool entry associated with an ORPS Report?

Yes

Is the event/issue related to a PAAA or WSH regulatory area?

Yes – Safety Basis and Quality

How do you determine if there are non-compliances?

- This is an ORPS Report Coordinate with the PAAA Program Office
- As this involves a PAAA subject, the PAAA Program Office will provide an institutional SME review

Identify and explain the noncompliance(s).

- 830.122(b)(1) Training and Qualification
- 830.122(e)(1) Performance and Work Processes
- 830.201 Safety Basis Performance of Work

Is the event NTS-reportable? YES

- Regulatory Noncompliance in Nuclear Safety regulatory area
- ORPS categorization Group 3A(2) Violation of a DSA hazard control





## Responsibilities (MRB)

- Develops and ensures implementation of organizational MRB charter.
- Determines discussion/agenda items, such as IAS and metrics reviews.
- Reviews/approves all high and moderate risk screenings.
- Confirms appropriate screening and risk categorization for environmental-related issues (<u>ISO 14001</u>, International Standard for Environmental Management Systems) and LLW/MLLW-related issues (<u>P409</u>, LANL Waste Management).
- Reviews/approves high and moderate risk issue causal analyses, extent of condition evaluations, corrective actions, action updates (including due dates, due date extensions, actionees, and action language), action/issue closures, and EE plans/reports.
- Reviews cross-organizational actions/issues to ensure appropriate assignment.
- Ensures MRB charters for new/restructured organizations are approved by the authorizing manager.
- Determines when issues meet high risk or have institutional impact, and escalate the issue to the IMRB level.



## Responsibilities (IRM)

- Completes <u>Course #38401</u>, Issues Management Process Training.
- Collaborates with IMC(s) to ensure issues are categorized appropriately.
- Ensures appropriate causal analysis and extent of condition evaluations are completed for high and moderate risk issues, and low risk issues as necessary.
- Develops or approves corrective actions to address all risk issues, assign appropriate actionee(s), and provide a viable action due date.
- Reviews completed corrective actions and OE to ensure adequacy and completion.
- Ensures an appropriate EE is performed for high and moderate risk issues, and low risk issues as necessary.
- Ensures actions/issues from independent and external assessment organizations requiring external approval are appropriately communicated.



## Responsibilities (IMC)

- Ensures <u>Course #38401</u>, Issues Management Process Training and <u>Course #38406</u>, Issues Management Tool Training, are completed before performing IMC duties.
- Acts as SME on IM process; assists MRB, IRMs, and actionees with IM implementation.
- Communicates IM process and tool changes.
- Manages IM data in the IM tool, including action/issue entry, tracking/updating action/issue statuses, and monitoring corrective actions.
- In coordination with IRM, completes initial screening and categorization by risk for identified issues.
- Prepares/presents actions/issues for management review.
- Supports MRB by monitoring and reporting action/issue status.
- Documents decision-making outcomes in MRB minutes.
- Works with IRMs and actionees to obtain appropriate action completion OE, and ensures appropriate
   OE is documented in the IM tool.
- Works with other organizational IMCs to reassign actions/issues and communicates reassignments as appropriate.
- Communicates with appropriate office about corrective actions and closures related to ORPS- or PAAA/WSH NTS-, or WSH-reportable events.
- Communicates with the IMRB CAS representative to add escalated issues (determined by the MRB) to the IMRB agenda, and prepares appropriate issue documentation.
- Partners with QPA-PA to ensure utilization of current process, tools, and procedures are implemented.





## Responsibilities (Actionee)

- Concurs with IRM on action(s) and associated completion date(s).
- Completes actions as directed and assigned.
- Prepares and presents timely, complete, and appropriate OE to the IRM and IMC to demonstrate action completion.
- Submits requests for revisions to action language and action due date extensions to IRMs.





## Questions





